

REMARKS

Claims 1, 6-14 are presently in the subject application.

Claims 2-5 have been cancelled without prejudice.

Claims 1, 6 and 7-10 have been amended to more adequately define and protect Applicants' invention. The amendments do not add new matter nor raise an additional issue and, accordingly, entry of these amendments is respectfully requested. In this regard, reference is made to the subject specification at page 12, bridging paragraph, and pages 16-17.

Claims 1 and 3-14 are rejected under 35 U.S.C. §§ 102(b) and (e) as being anticipated by Hora et al., U.S. Patent No. 5,730,969 ("HORA").

Claims 3-5 have been cancelled without prejudice and it is respectfully submitted that the remaining claims are not anticipated by HORA.

HORA does not reveal a construct of alginic acid polymer. HORA does not reveal at such construct having the medicament insulin associated with said polymer. Accordingly, HORA does not anticipate claims 1 and 6-14.

Anticipation under 35 U.S.C. § 102(b) and (e) means that a single prior art reference identically shows every element of the claimed invention – that is the claim being examined. HORA fails to this respect. Accordingly, allowance of claims 1 and 6-14 is respectfully requested.

Claims 1 and 3-14 are rejected under 35 U.S.C. § 102(b) and (e) as being anticipated by Baichwal, U.S. Patent No. 5,302,399 ("BAICHWAL").

Claims 3-5 have been cancelled without prejudice and it is respectfully submitted that the remaining claims are not anticipated, under 35 U.S.C. §§ 102(b) and (e), by BAICHWAL.

BAICHWAL does not reveal a construct of alginic acid polymer. BAICHWAL does not reveal at such construct having the medicament insulin associated with said polymer. Accordingly, HORA does not anticipate, under 35 U.S.C. §§ 102(b) and (e), claim 1 and 6-14 and allowance of these claims is respectfully requested.

Claims 1, 2 and 6-14 are rejected under 35 U.S.C. §§ 102(b) and (e), as being anticipated by Otagiri et al., U.S. Patent No. 5,302,399 ("OTAGIRI"). Claim 2 has been cancelled without prejudice and it is respectfully submitted that the remaining claims are not anticipated, under 35 U.S.C. §§ 102(b) and (e), by OTAGIRI.

OTAGIRI reveals an alginic acid gel bead carrier for a medicament. The alginic gel bead of OTAGIRI is made by reacting an alginic acid salt with a gelling agent, namely CaCl_2 . Reference in this regard is made to OTAGIRI at col. 7 – col. 8, claim 1. The medicament employed by OTAGIRI is not insulin but a beta-blocking agent, a calcium antagonist, an antihistamine agent, a diuretic, a vasodilative agent and an antitusive (OTAGIRI, at col. 2, lines 20-30).

OTAGIRI does not reveal a construct of alginic acid polymer and insulin, as prepared by Applicants. The alginic acid polymer is not gelled with a gelling agent, i.e., CaCl_2 . In this regard, Applicants' invention, in claims 1 and 6-14, is defined as being prepared from a preparation "consisting essentially of" alginic acid polymer and insulin. The transitory term "consisting essentially of," as opposed to the term "comprising" or "consisting of" in a claim, is a term of art having an accepted meaning in chemical as well as pharmaceutical patent practice. *Carter-Wallace, Inc. v. Gillette Co.*, 531 F. Supp. 840 n.29, 211 U.S.P.Q. 499, 527 n.29 (Mass. 1981).

A group of the Primary Examiners of the Patent Office, for their own guidance, adopted a code of terms to aid uniformity of practice, which explains that claim terms are to be interpreted as follows:

1. “comprising” and “comprising essentially” as leaving the claim open for the inclusion of unspecified ingredients even in major amounts;
2. “consisting of” as closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith, and
3. recital of “essentially” along with “consisting of” as rendering the claim open only for the inclusion of unspecified ingredients which do not materially affect the basic and novel characteristics of the composition.

Ex parte Davis & Tuukkanen, 80 U.S.P.Q. 448, 450 (POBA 1948). The Court of Appeals for the Federal Circuit (“CAFC”) has adopted this interpretation, i.e., the term “consisting essentially of” excludes ingredients that materially affect the basic and novel characteristics of the claimed composition. *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 224 U.S.P.Q. 409 (Fed. Cir. 1984); *Water Technologies Corp. v. Calco Ltd.*, 850 F.2d 660, 7 U.S.P.Q.2d 1097 (Fed. Cir. 1988) (the phrase “does not exclude the addition of an ingredient that does not materially affect the invention’s characteristics”). Reference is also made to *PPG Industries v. Guardian Industries Corp.*, 48 U.S.P.Q.2d 1351, 1354 (Fed. Cir. 1998), citing *Ex parte Davis*, 80 U.S.P.Q. 448, 449-450 (POBA 1948).

Although “consisting essentially of” is typically used and defined in the context of compositions of matter, there is nothing intrinsically wrong with the use of such language as a modifier of method steps. Accordingly, the language of “consisting essentially of,” when used as a modifier of method steps, renders the claims open only to the inclusion of steps that do not materially affect the basic and novel characteristics of the claimed method. *Ex parte Hoffman*, 12 U.S.P.Q.2d 1061, 1063, 1064 (B.P.A.I. 1989).

Accordingly, the alginic acid polymer excludes the alginic acid gel beads of OTAGIRI produced by the gelling agent CaCl_2 . Claims 1 and 6-14 are not anticipated, under 35 U.S.C. §§ 102(b) and (e), by OTAGIRI and allowance of these claims is respectfully requested.

Claims 3, 4 and 5 are rejected under 35 U.S.C. § 112, second paragraph. These claims have been cancelled without prejudice.

The Examiner is hereby authorized to call the undersigned attorney of record "collect" on any matter connected with this application. The telephone number is area code (212) 588-0800. In the absence of the undersigned attorney of record, the call will be accepted by any attorney empowered in this application.

Respectfully submitted,
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